

**REMARKS**

Reconsideration is respectfully requested in view of Applicants' amendments and remarks submitted herewith, along with a 1.132 Declaration by Dr. Shigehisa, a co-inventor, with literature reference attached thereto.

With respect to the final rejection dated September 24, 2002, Applicants have the following comments.

With respect to the Sequence Compliance paragraph at the middle of page 2, Applicants have amended pages 14-15 of the application to include on page 14 the sequence identifier numbers for the two sequences listed thereon.

Beginning with the last paragraph of page 2 of the Office Action and carrying over to the top of page 4 of the Office Action, the Examiner again rejects all claims under the first paragraph of 35 U.S.C. § 112 on the basis of lack of enablement to make and/use the invention. With respect to this rejection, Applicants submit herewith the Declaration of Dr. Shigehisa. In the Declaration of Dr. Shigehisa, two experiments are set forth clearly showing that the transgenic pig of the present invention can overcome hyperacute rejection in pig-to-primate xenotransplantation. Furthermore, Dr. Shigehisa refers to specific portions of the application as filed, which to the skilled artisan clearly relate to the enablement of the transgenic non-human mammals being claimed for use in xenotransplantation. In particular, the Examiner is referenced to the Declarants specific citation to page 19, lines 11-15 of the specification and the teachings of the present application regarding clear expression of the hDAF protein and the function thereof, the latter involving a cell-lysis assay, i.e., prevention of complement activation.

AMENDMENT UNDER 37 C.F.R. § 1.114(C)  
U.S. APPLN. NO. 09/462,740

In view of the above comments and the 1.132 Declaration submitted herewith, Applicants respectfully request that the first paragraph 35 U.S.C. § 112 rejection be reconsidered and withdrawn.

Beginning with page 4 of the Office Action, the Examiner maintains a rejection of all claims under 35 U.S.C. § 103 as being unpatentable over Rosengard taken with Toyomura.

The promoter in claim 1 is now defined as a part of Sequence ID No. 1 (i.e., base No. 4498 to 5397). See page 12, line 15 of the application. The inventors found that such base sequence is very effective to promote expression of DAF in an organ and tissue of the transgenic mammal. In this respect, please see reference D1 (MOLECULAR REPRODUCTION AND DEVELOPMENT 61: 302-311, 2002) enclosed with the 1.132 Declaration. As shown in D1, transgenic pigs were not obtained with the 5.4kb promoter of pMCP + hDAF construct, but only with the 0.9kb promoter. These findings are neither disclosed nor suggested by Toyomura. Therefore, the present invention is not obvious over Rosengard and Toyomura.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.114(C)  
U.S. APPLN. NO. 09/462,740

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Louis Gubinsky  
Registration No. 24,835

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: October 22, 2003